



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0507; FRL-9353-7]

RIN 2070-ZA16

Dicloran and Formetanate; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking certain tolerances for the fungicide dicloran and the insecticide formetanate hydrochloride in follow-up to amended registrations that deleted specific uses, leaving no dicloran and formetanate hydrochloride registrations for those uses. Also, in accordance with current Agency practice, EPA is making minor revisions to the tolerance expressions for dicloran and formetanate hydrochloride and to specific tolerance nomenclatures for dicloran.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0507, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open

from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; email address: nevola.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding

the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011- 0507 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-

OPP-2011- 0507, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background

A. What Action is the Agency Taking?

In the **Federal Register** of March 28, 2012 (77 FR 18748) (FRL-9340-9), EPA issued a rule that proposed to revoke certain tolerances for the fungicide dicloran and the insecticide formetanate hydrochloride in follow-up to amended registrations that deleted specific uses, leaving no dicloran and formetanate hydrochloride registrations for those uses, and make minor revisions to the tolerance expressions for dicloran and formetanate hydrochloride and to specific tolerance nomenclatures for dicloran. Also, the proposed rule of March 28, 2012 provided a 60-day comment period which invited public comment for consideration and for support of tolerance retention under FFDCA standards.

In this final rule, EPA is revoking certain tolerances because either they are no longer needed or are associated with food uses that are no longer registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in the United States. Those instances where registrations were canceled were because the registrant failed to pay the required maintenance fee and/or the registrant voluntarily requested cancellation of one or more registered uses of the pesticide active ingredient. The tolerances revoked by this final rule are no longer necessary to cover residues of the relevant pesticides in or on domestically treated commodities or commodities treated outside but imported into the United States. It is EPA's general practice to issue a final rule revoking those tolerances and tolerance exemptions for residues of pesticide active ingredients on crop uses for which there are no active registrations under FIFRA, unless any person in comments on the proposal indicates a need for the tolerance or tolerance exemption to cover residues in or on imported commodities or legally treated domestic commodities.

EPA has historically been concerned that retention of tolerances that are not necessary to cover residues in or on legally treated foods may encourage misuse of pesticides within the United States.

Generally, EPA will proceed with the revocation of these tolerances on the grounds discussed in Unit II.A. if one of the following conditions applies:

1. Prior to EPA's issuance of a FFDCA section 408(f) order requesting additional data or issuance of a FFDCA section 408(d) or (e) order revoking the tolerances on other grounds, commenters retract the comment identifying a need for the tolerance to be retained.
2. EPA independently verifies that the tolerance is no longer needed.

3. The tolerance is not supported by data that demonstrate that the tolerance meets the requirements under the Food Quality Protection Act (FQPA).

In response to the proposed rule published in the **Federal Register** of March 28, 2012 (77 FR 18748), EPA received no comments during the 60-day public comment period. Therefore, EPA is finalizing the actions proposed concerning dicloran and formetanate hydrochloride in the **Federal Register** of March 28, 2012 (77 FR 18748) (FRL-9340-9). For a detailed discussion of the Agency's rationale for the finalized tolerance actions, refer to the proposed rule of March 28, 2012.

B. What is the Agency's Authority for Taking this Action?

EPA's general practice is to revoke tolerances for residues of pesticide active ingredients on crops for which FIFRA registrations no longer exist and on which the pesticide may therefore no longer be used in the United States. EPA has historically been concerned that retention of tolerances that are not necessary to cover residues in or on legally treated foods may encourage misuse of pesticides within the United States. Nonetheless, EPA will establish and maintain tolerances even when corresponding domestic uses are canceled if the tolerances, which EPA refers to as "import tolerances," are necessary to allow importation into the United States of food containing such pesticide residues. However, where there are no imported commodities that require these import tolerances, the Agency believes it is appropriate to revoke tolerances for unregistered pesticides in order to prevent potential misuse.

C. When Do These Actions Become Effective?

As stated in the **DATES** section, this final rule is effective [*insert date of publication in the Federal Register*]. However, EPA is revoking the dicloran tolerance

on potato with an expiration/revocation date of December 31, 2014 and the formetanate hydrochloride tolerances on apple; apple, wet pomace; peach; and pear with expiration/revocation dates of December 31, 2013. The Agency believes that these expiration/revocation dates allow users to exhaust stocks and allow sufficient time for passage of treated commodities through the channels of trade.

Any commodities listed in the regulatory text of this document that are treated with the pesticides subject to this final rule, and that are in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(1)(5), as established by FQPA. Under this unit, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA.
2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates that the pesticide was applied to such food.

III. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and

Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for formetanate hydrochloride or MRL for dicloran in or on potatoes.

IV. Statutory and Executive Order Reviews

In this final rule, EPA revokes specific tolerances established under FFDCA section 408. The Office of Management and Budget (OMB) has exempted this type of action (i.e., a tolerance revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled “*Regulatory Planning and Review*” (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, entitled “*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*” (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled “*Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*” (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045,

entitled “*Protection of Children from Environmental Health Risks and Safety Risks*” (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-13, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020) (FRL-5753-1), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis and available information concerning the pesticides listed in this rule, the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. (This Agency document is available in the docket of the proposed rule, as mentioned in Unit II.A.). Furthermore, for the pesticides named in this final rule, the Agency knows of no extraordinary circumstances that exist as to the present revocations that would change EPA's previous analysis. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government

and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “*Federalism*” (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled “*Consultation and Coordination with Indian Tribal Governments*” (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 2, 2012.

Steven Bradbury,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.200 to read as follows:

§ 180.200 Dicloran; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide dicloran, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only dicloran, 2,6-dichloro-4-nitroaniline, in or on the commodity.

Commodity	Parts per million	Expiration/Revocation Date
Apricot	20	None
Bean, snap, succulent	20	None
Carrot, roots	10	11/2/11
Celery	15	None
Cherry, sweet	20	None
Cucumber	5	None
Endive	10	None
Garlic	5	None
Grape	10	None
Lettuce	10	None
Nectarine	20	None
Onion	10	None
Peach	20	None
Plum, prune, fresh	15	None
Potato	0.25	12/31/14
Rhubarb	10	None
Sweet potato, roots	10	None
Tomato	5	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

3. Revise § 180.276 to read as follows:

§ 180.276 Formetanate hydrochloride; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide formetanate hydrochloride, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only formetanate hydrochloride, *N,N*-dimethyl-*N'*-[3-[[[(methylamino)carbonyl]oxy]phenyl]methanimidamide hydrochloride, in or on the commodity.

Commodity	Parts per million	Expiration/Revocation Date
Apple	0.50	12/31/13
Apple, wet pomace	1.5	12/31/13
Grapefruit	1.5	None
Lemon	0.60	None
Lime	0.03	None
Nectarine	0.40	None
Orange	1.5	None
Peach	0.40	12/31/13
Pear	0.50	12/31/13
Tangelo	0.03	None
Tangerine	0.03	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2012-16961 Filed 07/10/2012 at 8:45 am; Publication Date: 07/11/2012]